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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,310	01/09/2001	Pierre Jean Francois Layrolle	04148-00006	7859

7590 11/05/2002  
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EXAMINER

LAMB, BRENDA A

ART UNIT PAPER NUMBER

1734

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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9

Below is a communication from the EXAMINER in charge of this application  
COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.  
Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 707.07(f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (see NOTE below);
- (b) ☐ they raise the issue of new matter. (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE:  
The registration of an aperture operatively connected to the reactor presents a new issue requiring further consideration and/or search since Applicant has never before recited an aperture operatively connected to the reactor.

4. ☐ Applicant's reply has overcome the following rejection(s):

5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: \_\_\_\_\_
- Claim(s) objected to: \_\_\_\_\_
- Claim(s) rejected: 27-46 over the art of record.
- Claim(s) withdrawn from consideration: \_\_\_\_\_
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other: \_\_\_\_\_

Brenda A. Lamb  
BRENDA A. LAMB  
PRIMARY EXAMINER

# Office Action Summary

Application No.

09/757,310

Applicant(s)

Layrolle et al

Examiner

LAMB

Group Art Unit

1734

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/24/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 27-46 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 27-46 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-32, 35-40 and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al.

Benoit et al teaches the design of coating apparatus having a reactor vessel R-2, heating element TC, stirrer, a plurality of inlets/outlets connected to the reactor and a controlled source of carbon dioxide operatively connected to an inlet (see column 11, lines 1-53 and Figure 1). Benoit et al fails to teach an implant support and end use of coating apparatus for coating an implant. However, it would have been obvious to modify Benoit et al apparatus by providing a support for the implant which is operatively connected to the vessel since it is conventional to operatively connect to the reactor vessel or coating vessel a support for an article being treated which includes a hook for obvious reason to provide greater control of movement of the articles

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being treated or control and therefore greater control of the coating process. Further, it would have been obvious the Benoit et al apparatus is structured and arranged to coat a variety of materials including those particulate materials to be used as an implant and especially since it is known to implant pharmaceutical compositions (see column 6, lines 34-56). The recitation of an outlet to avoid increasing internal pressure of the reactor vessel does not further limit applicant's invention over Benoit et al in that Benoit et al has a plurality of outlets which include drain valve (drain) which as depicted drains contents from the reactor vessel R-2 and exhaust valve to atmosphere and each of these valves is obviously configured to avoid increasing internal pressure of the reaction by draining/exhausting the contents of the reactor. With respect to claims 27-28, Benoit teaches the stirrer is a magnetic transmission stirrer and obvious the stirrer is capable of being controlled such that stirrer rotates at 100 rpm given the wide range of agitation speeds set forth in the Examples 1-25. With respect to claims 30-31, Benoit et al teaches valve V-2 to control flow of carbon dioxide to the reaction vessel. Although Benoit et al fails to teach the valve is a solenoid valve or an electro valve, it would have been obvious to use any conventional type of valve as valve (v-2) in the Benoit apparatus including a solenoid or electro-valve for the obvious advantage over manual control valves. With respect to claim 35-36, Benoit et al teaches in the examples that volume/capacity of the reactor vessel/autoclave is 1.5 liters. With respect to claims 37 and 39, Benoit et al teaches at column 11, lines 48-53 teaches that reservoir or reactor vessel is equipped with separate cooling and heating jacket (TC) or is double jacketed as shown in Figure 1 to obtain various temperatures. Benoit et al also teaches in examples 1-25 that the temperature of the reaction vessel/ autoclave is within the scope of the claims. With respect to claim 38, Benoit et al teaches at column 11, lines 13-25

fluid can be heated prior to circulation of the fluid to the reactor vessel/reservoir/autoclave thereby reading on a thermocirculator. With respect to claims 41 and 42, Benoit et al teaches pressure and temperature within the reaction vessel/autoclave is adjusted in a controlled manner (see column 8, line 59 to column 9, line 24). Benoit et al fails to teach an automated system for controlling temperature and pressure as a function of time but obvious to do so for advantage of automation of a process step of measuring and controlling process conditions. With respect to claims 43-44, Benoit et al teaches at column 11, line 53 filtering devices are associated with Benoit coating apparatus but fails to teach the filtering device is a membrane filter having a pore size of 0.2 mm. However, it would have been obvious to provide as the filtering device in the Benoit et al apparatus a conventional filtering device, a filter membrane cell, and optimize pore size of the membrane cell such that are within the scope of the claim dependent on end use of apparatus. With respect to claim 32, recitation of electrode operatively connected to reactor/autoclave does define applicant's invention over Benoit et al obvious to modify to include an electrode since conventional to measure result effect process parameters in a reactor such as pH using a conventional pH measuring means, an electrode. With respect to claim 45, same rejection applied to claims 1, 27, 39, 30 and 32 is applied here. With respect to claim 46, same rejection applied to claim 45 is applied here. Benoit et al teaches as discussed above temperature and pressure of the vessel/ autoclave is adjusted in a controlled manner (See column 8, line 59 to column 9 line 24). Benoit et al fails to teach automated system for controlling temperature and pressure as a function of time but obvious to do so for advantage of automation of a process step of measuring and controlling process conditions. With respect to claim 29,

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components into the vessel including a porous sparger to more thoroughly gaseous components such as the Benoit et al carbon dioxide in a <sup>reactor</sup> vessel.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al in view of Roberts et al.

Benoit et al is applied for the reasons noted above. Benoit et al fails to disclose the reactor vessel includes a coating to avoid deposition or incrustation of carbonate and calcium phosphate or is fashioned from stainless steel. However, Roberts et al providing a lining of polytetrafluoroethylene on a metal reaction vessel which is conventionally a stainless steel material to provide greater corrosion resistance of the reaction vessel. Therefore, it would have been obvious to provide as the reaction vessel in the Benoit apparatus a polytetrafluoroethylene lining to a conventional metal vessel such as stainless steel for the advantage of the polytetrafluoroethylene coated metal vessel-increased resistance to corrosion. The recitation that the coating avoids deposition or incrustation of carbonated calcium phosphate does not define applicant's invention over Benoit et al as modified since the Roberts polytetrafluoroethylene coating is within the scope of coating disclosed by applicant in the instant specification.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al in view of Roberts et al in view of Wheeler et al.

Benoit fails to teach a porous sparger. However, it would have been obvious to use any conventional means to carbon dioxide into the Benoit et al reactor vessel by providing a porous sparger since it is conventional to introduce gaseous components into a reactor to more thoroughly disperse the gaseous component in a vessel obviously as a result of the production of microbubbles by the porous sparger.

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Claims 33, 42 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation that the reactor includes a coating to avoid deposition or incrustation of carbonated calcium phosphate in claim 33 is vague and indefinite since applicant's device for coating an implant is silent as to the presence of any composition which might form calcium phosphate coating while only claiming a source of carbon dioxide which is not capable itself of forming a coating of calcium phosphate. The recitation in claim 42 and 46 of a automation system to measure, record and/or control parameters such as calcium concentration, phosphate concentration and carbonate concentration in claim 42 and 46 are vague and indefinite since applicant's device is silent as to the presence of any composition which might enable one to measure calcium concentration phosphate concentration and carbonate concentration while only claiming a source of carbon dioxide.

Applicant's arguments filed 4/24/02 have been considered but they are not persuasive.

Applicant's argument that Benoit et al fails to teach a outlet which avoids increasing internal pressure of the vessel is found to be no-persuasive since Benoit et al has a plurality of outlets which include drain valve (drain) which as depicted drains contents from the reactor vessel R-2 and exhaust valve to atmosphere and each of these valves is obviously configured to avoid increasing internal pressure of the reaction by draining/exhausting the contents of the reactor. Note the recitation of an outlet which avoids increasing internal pressure of the vessel is so broad that it reads on any outlet from the vessel which is in fluid communication with ambient air or an in fluid communication with a source of fluid at a lower pressure than the vessel.



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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

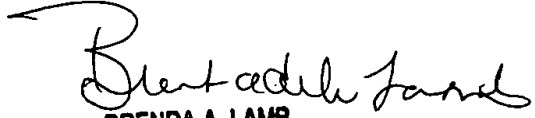
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hammer, Garrison and Murray each show various ways of supporting an article in a tank which includes a hook.

Any inquiry concerning this communication should be directed to Brenda Lamb at telephone number 703 308-2056. The examiner can normally be reached on Monday and Wednesday through Fridays with first Tuesday of the bi-week off.

Examiner Lamb/ng

August 14, 2002

  
**BRENDA A. LAMB**  
**PRIMARY EXAMINER**  
**GROUP 1300**